Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698192	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Special Procedures Laboratory (Spl)	7200 Cambridge Street Rm B10-609, Houston, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Review of 2017 and 2018 proficiency testing records and interview of facility personnel found that testing personnel and the laboratory director failed to attest to the routine integration of proficiency specimens specimens into routine, patient workloads for semen analysis for four of four testing events. The findings included: 1. Review of the American Association of Bio Analysts (AAB) proficiency testing records for 2017 and 2018 found that the laboratory participated in a proficiency testing event for Sperm Viability and Andrology in Embryology (nonregulated analytes) to ensure the accuracy of results. The laboratory failed to document physical signatures of the laboratory director and testing personnel performing the proficiency event, in four of four testing events. 2. Interview of the general supervisor conducted on January 23, 2019 at 10:43 AM confirmed that electronic signatures were used and not physical signatures.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on a review of policies and procedures, competency assessment records and interview of facility personnel it was revealed that the laboratory failed to have a procedure to assess the competency of all consultants and testing personnel performing semen analysis procedures. The findings included: 1. Review of policies and procedures found there was no procedure available for review for assessing the competency of the consultants, supervisors or testing personnel. The policy for the competency assessment of testing personnel, supervisors and consultants was requested but not provided. 2. Review of personnel files found no documentation of semiannual and annual competency assessments for four of four testing personnel listed on the CMS report 209 Laboratory Personnel Report, and the general supervisor. 3. Interview of the general supervisor conducted on January 23, 2019 at 9: 33 AM confirmed that the laboratory did not have a written or electronic version of a competency assessment policy/procedure, and semiannual and annual competency assessments had not been documented for testing personnel. He went on to say at 10: 35 AM that he thought "scanning the comparisons and proficiency testing was enough.".
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Review of policies and procedures, personnel records and interview of facility personnel found that the laboratory failed to ensure that all policies and procedures had been approved , signed and dated by the current laboratory director. The findings included: 1. Review of policies and procedures found in the notebook labeled lab procedure manual found no documentation of approval by the current laboratory director for 24 of 24 policies and procedures. 2. Review of personnel records found that the current laboratory director was hired in June 25, 2018. 3. Interview of the general supervisor conducted on March 5, 2019 at 10:42 AM confirmed the Laboratory Director had not approved the procedures currently in use by testing personnel.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Review of policies and procedures, 2017 and 2018 maintenance records and interview facility personnel found that the laboratory failed to document maintenance procedures for the ventilation hood as defined in their own written procedure. The

	findings included: 1. Review of the policy and procedure titled temperatures, levels, and preventive maintenance found on page 20 under the heading ventilation hood: "Daily: clean the interior and change the bench paper if the hood was in use. Ensure before the end of the day that the interior light is switched forum florescent to germicidal. Monthly: clean the exterior and glass shield cover. Ensure shield is at correct level. Note any corrections. Quarterly: check the auxiliary power supply. Ensure function of switches. Note corrections. Annual: contact Baylor environmental safety for annual inspections." 2. Review of the ventilation hood. Preventive maintenance and quality control records for 2017 in 2018 found quarterly maintenance procedures documented for: February 13, 2017, December 19, 2017 and January 8, 2017. There was no documentation of annual safety inspections for 2017. There were no records available for review for maintenance in 2018. 3. Interview of the general supervisor conducted at 10:43 AM on January 23, 2019 confirmed the above findings.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control records and staff interview, it was revealed the laboratory failed to test at least one quality control each eight hours of operation when analyzing patient specimens for semen analysis. The findings included: 1.Review of quality control records from March 2017, and October through December 2018 found no documentation of quality control performance on one of 31 days in October and one of 31 days in December 2018. There was no quality control documentation for October 27, 2018 with one patient specimen tested. There was no quality control documentation for December 24, 2018 with one patient specimen tested. 2. Interview of the general supervisor conducted on January 23, 2019 at 11:29 AM confirmed the above findings. He stated that one person comes in at 7:30 AM to start maintenance and perform quality control procedures.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Review of laboratory records and interview of facility personnel found that the laboratory director failed to notify the State Agency within 30 days of a change in laboratory director. (See D 8103)
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel found that the laboratory director failed to ensure that an approved procedure was available to assess the competency of all supervisors, consultants and testing personnel. (See D5209)
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's written polices and procedures, and staff interview, revealed the laboratory director failed to ensure an approved procedure manual was available to testing personnel for performing semen analysis. (see D5407)
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

	This STANDARD is not met as evidenced by: Review of the CMS 116,personnel records and Interview of facility personnel found that the laboratory failed to notify the state agency within 30 days when a change in the laboratory director occurred. The findings included: 1. Review of the CMS 116 Application for Certification provided during the inspection found the name of the Laboratory Director differed than the name on the CLIA certificate of Compliance issued June 21, 2016 . 2. Review of personnel records found that the Laboratory director hired June 25, 2018 3. Interview of the General Supervisor conducted on January 23, 2019 at 10:22 AM confirmed that the laboratory director was hired in March, 2018 and he had not notified the State agency of the change in Laboratory Director.